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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,907	01/20/2004	Mark W. Kroll	A04P1004	4324

36802 7590 09/26/2006

PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER	
REIDEL, JESSICA L	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

NT

Office Action Summary	Application No.	Applicant(s)	
	10/761,907	KROLL ET AL.	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16 and 23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,14-16 and 23* is/are rejected.

7)☒ Claim(s) *13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgement is made of Applicant's Amendment, which was received by the Office on July 18, 2006. Claims 17-22 have been cancelled. Claim 23 has been added. Claims 1-16 and 23 are pending.

Specification

2. In view of the response filed on July 18, 2006, the objections made to the specification in the Office Action of April 19, 2006 have been withdrawn.

Claim Objections

3. In view of the response filed on July 18, 2006, the objections made to the claims in the Office Action of April 19, 2006 have been withdrawn.

Claim Rejections - 35 USC § 112

4. In view of the response filed on July 18, 2006, the 35 U.S.C. 112 rejections made in the Office Action of April 19, 2006 have been withdrawn.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-3, 5-7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tarjan (U.S. 4,787,389) in view of Norton et al. (U.S. 2004/0243183) (herein Norton). As to Claims 1-2 and 6, Tarjan discloses a cardiac stimulation apparatus, read as an implantable prophylactic pacemaker/defibrillation device (see Tarjan Fig. 1 and Abstract) comprising a conventional pacing circuit and an antitachycardia circuit 12, collectively read as pacing pulse generation circuitry (see Tarjan column 2, lines 36-57 and column 3, lines 41-45) and defibrillation shock generation circuitry 58. It is inherent or at least obvious to one having ordinary skill in the art that the defibrillation shock generation circuitry 58 of Tarjan includes a shock capacitor for delivering a high-energy pulse of about 15 to 30 joules (see Tarjan Fig. 1 and column 4, lines 5-8 and lines 48-65). Tarjan also discloses that the implantable prophylactic pacemaker/defibrillation depicted in Tarjan Fig. 1, further comprises a first power source 14 operative to provide power for the pacing pulse generation circuitry and a second power source (within the defibrillator 56) permanently electrically decoupled from the pacing pulse generator and operative to provide power only for the defibrillation shock generation circuitry 58 (see Tarjan Figs. 1-3, column 1, lines 41-68, column 4, lines 1-13, column 5, lines 65-68 and column 6, lines 1-5).

The Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the implantable prophylactic pacemaker/defibrillation device of Tarjan is capable of providing

sufficient power for delivering defibrillation shocks only in response to a single episode of ventricular fibrillation (see Tarjan column 4, lines 48-68 and column 5, lines 1-5). Tarjan discloses the claimed invention as discussed above except it is not specified that the defibrillation shock generation circuitry 58 include non-reformation based charging circuitry for charging a tantalum capacitor without prior capacitor reformation.

Norton, however, discloses an implantable medical device, such as a defibrillator (see Norton Fig. 1) including a tantalum capacitor, which does not require any prior capacitor reformation (see Norton page 1, paragraphs 12-15). Norton further discloses that an implantable defibrillator that uses a tantalum capacitor that does not require any prior capacitor reformation provides an implantable medical device that has extended battery life (due to the elimination of non-therapeutic charging) and greatly improves efficiency of capacitor charging (see Norton page 1, paragraphs 2, 5, 7 and 15, page 2, paragraphs 16, 26-29 and pages 3-4, paragraph 51). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Tarjan in view of Norton to include non reformation based defibrillation generation circuitry with a tantalum capacitor in order to extend battery life and greatly improve efficiency of capacitor charging.

7. As to Claim 3, the previously modified Tarjan reference discloses the claimed invention as discussed above except that it is not specified that the shocking capacitor is an aluminum oxide capacitor. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Tarjan, with an aluminum oxide shocking capacitor since it was known in the art that aluminum oxide capacitors are used to provide high energy output in shocking circuitry. It addition, Applicant discloses at page 2, paragraph 4 that

the use of aluminum oxide capacitors is well known in the implantable pacemaker/defibrillator art.

8. As to Claim 5, it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison,* 69 USPQ 138. Tarjan specifies that the number of high-energy pulses, which the defibrillation shock generation circuitry 58 can deliver, is limited by the second power source and can be up to one hundred (see Tarjan column 5, lines 2-5). The Examiner takes the position that Tarjan is thusly "capable of " delivering up to six defibrillation shocks in response to a single episode of ventricular fibrillation.

9. As to Claim 7, Tarjan specifies that the first power source 14 (within pacer 10) is a low rate, long life power source and the second power source (within defibrillator 56) is a high rate, short life power source (see Tarjan column 5, lines 66-68 and column 6, lines 1-5).

10. As to Claim 9, Tarjan specifies that the pacer 10 is capable of being programmed. The Examiner takes the position that a pacer that is programmed to an "automatic antitachycardia mechanism" comprises programmable control circuitry operative to control the pacing pulse generation circuitry (conventional circuitry and the antitachycardia circuit 12). Tarjan further specifies that the pacer 10 of the implantable prophylactic pacemaker/defibrillation device also controls the defibrillation shock generation circuitry 58 via a coded series of pulses sent from the pacer through lead 16 and into the tissue through electrodes 86, 88 (see Tarjan column 4, lines 30-48).

11. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tarjan in view of Norton as applied to claim 1 above, and further in view of Official Notice. The previously modified Tarjan reference discloses the claimed invention as discussed above except that it is not specified that the defibrillation shock generation circuitry and the second power source are configured to slowly charge the capacitor over a period of time not less than 11 seconds prior to delivery of a first defibrillation shock. The Examiner takes Official Notice that it is well known in the art of implantable defibrillators to slowly charge defibrillation capacitors over a period of time not less than 11 seconds and usually not greater than 30 seconds to allow the capacitors sufficient time to fully charge without unnecessarily over-draining the battery and without taking too long to treat an episode of fibrillation. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the defibrillation shock generation circuitry and second battery of Tarjan in view of Norton and Official Notice to slowly charge the capacitor over a period of time not less than 11 seconds prior to delivery of a first defibrillation shock in order to provide adequate capacitor charging time without taking too long to treat the fibrillation and without excessive drain on the second power source.

12. Claims 10 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tarjan in view of Norton as applied to claim 1 above, and further in view of Anderson et al. (U.S. 5,376,103) (herein Anderson). As to Claims 10 and 15-16, the previously modified Tarjan reference discloses the claimed invention as discussed above except that it is not specified that the defibrillation shock generation circuitry is selectively coupled to a right ventricular coil electrode and a device housing electrode for delivering a ventricular defibrillation shock to the heart of a patient.

Anderson, however, discloses an implantable defibrillator pulse generator 32 which utilizes the metal case as an electrode and is operative to selectively supply unique patters of monophasic, biphasic or pairs of electrical pulses to coil electrodes located at the right ventricular apex (RVA) and at the superior vena cava (SVC). Anderson discloses that such an implantable defibrillator pulse generator 32 which can selectively apply pulses between the right ventricular apex coil electrode (which is capable of directing current through the bulk of the right ventricle), the housing electrode and the SVC electrode provides a wide range of polarity pattern and discharge-axis options for sequential defibrillation pulses, while eliminating the need for a subcutaneous-patch electrode (see Anderson Abstract, column 4, lines 45-58, column 6, lines 19-68 and column 7, lines 1-7). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify defibrillation shock generation circuitry of Tarjan in view of Norton and Anderson to selectively couple a right ventricular coil electrode, a SVC coil electrode and a device housing electrode for delivering ventricular defibrillation shocks to the heart of a patient in order to provide a highly effective polarity pattern and discharge-axis useful in sequential defibrillation shock techniques and to eliminate the need for a subcutaneous-patch electrode to better the invention.

13. As to Claim 14, the previously modified Tarjan reference discloses the claimed invention as discussed above except that it is not specified that the pacing pulse generation circuitry is configured to provide pacing pulses between a right ventricular tip electrode and a right ventricular coil electrode. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pacing pulse generation circuitry of Tarjan in view of Norton and Anderson to selectively supply pacing pulses between a right ventricular tip

electrode and a right ventricular coil electrode since it was known in the art that such a modification is used to either provide a large area of electrical pacing pulses (provided by the large surface are of the coil) or to provide a backup ventricular pacing modality in case the conductor connecting the right ventricular tip electrode becomes damaged and is no longer capable of adequately pacing the ventricle.

14. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tarjan in view of Norton and Anderson as applied to claims 1 and 10 above, and further in view of Schuelke et al. (U.S. 5,755,742) (herein Schuelke). The previously modified Tarjan reference discloses the claimed invention as discussed above except it is not specified that the pacing pulse generation circuitry is selectively coupled to ventricular tip and ring electrodes and right atrial tip and ring electrodes for delivering pacing pulses to the heart of a patient.

Schuelke, however, teaches that it is well known for an implantable pacemaker/cardioverter/defibrillator 100 to be capable of selectively applying pacing/cardioversion/defibrillation pulses/shocks between different electrode configurations. Schuelke further teaches that it is well known in the art to selectively couple ventricular tip 126 and ring 124 electrodes and right atrial tip 148 and ring electrodes 144 for delivering pacing pulses to the either the ventricle or the atrium of a patient (see Schuelke Figs. 1-2, column 6, lines 32-67, column 7, lines 1-46 and lines 58-67 and column 8, lines 1-16). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pacing generation circuitry of Tarjan in view of Norton, Anderson and Schuelke to selectively couple ventricular tip and ring electrodes and right atrial tip and ring electrodes for delivering

pacing pulses to both the atrium and the ventricle of a patient to better the inventions capabilities of eliminating rhythm disturbances occurring in either the atrium or ventricle.

15. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tarjan in view of Norton, Anderson and Schuelke applied to claims 1, 10 and 11 above, and further in view of Regna (U.S. 4,796,630). The previously modified Tarjan reference discloses the claimed invention as discussed above except it is not specified that shunt diodes interconnect the right ventricular tip and ring electrodes and right atrial tip and ring electrodes, respectively.

Regna, however, discloses a cardiac pacemaker that has combined defibrillation and electrosurgery protection (see Regna Abstract). Regna further discloses that a protection circuit interposed between a tip 36 and ring 38 electrodes including a zenor diode, read as a shunt diode 42 (see Regna Fig. 2 and column 3, lines 1-11). Regna further discloses that such a protection circuit may be utilized with a dual chamber pacemaker and that the shunt diode 42 protects the pacing circuitry from any defibrillation shock energies that may be applied across the heart of the patient (see Regna column 1, lines 35-52 and column 3, lines 50-60). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Tarjan in view of Norton, Anderson and Schuelke to include shunt diodes interconnected between the right ventricular tip and ring electrodes and right atrial tip and ring electrodes, respectively in order to provide defibrillation and electrosurgery protection to the pacing pulse generation circuitry.

16. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tarjan in view of Norton as applied to claim 1 above, and further in view of Pilz et al. (U.S. 6,044,295) (herein Pilz) and Marincic et al. (U.S. 5,558,962) (herein Marincic). Applicant differs from the

previously modified Tarjan reference in that the first power source is a polycarbon monofluoride (CF_X) power source (as opposed to the Li/I first power source of Pilz). The Examiner considers the use of CF_X power sources in implantable medical devices to be conventional and well known in the art with Marincic being but one example. The Examiner considers the use of lithium manganese dioxide ($LiMnO_2$) to be conventional and well known in the art with Pilz being but one example.

17. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Altman (U.S. 5,545,183) in view of Pilz. Altman discloses an implantable pacemaker/defibrillation device (see Altman Figs. 2-3 and column 3, lines 5-53) comprising pacing pulse generation circuitry 40, defibrillation shock generation circuitry 43, a tip electrode 12 and ring electrode 18 for delivering pacing pulses and a coil electrode 23 for delivering shocking pulses. Altman further discloses that the device comprises a switch 52 operative to hold the ring electrode 18 at a voltage equal to that of the coil electrode 23 during shocking pulse delivery (see Altman Figs. 1 and 3, column 4, lines 33-52, column 5, lines 25-67 and column 6, lines 1-32). It is inherent that switching matrix 50 and switch 52 are also operative to hold the ring electrode 18 at a voltage relative to the tip electrode 12 to deliver a pacing pulse, since this is the traditional bipolar arrangement for delivering pacing pulses and since both tip and ring electrodes 12, 18 are supplied by a single pacemaker circuit 40. Altman discloses the claimed invention as discussed above except that it is not specified that the device comprise a first power source operative to power the pacing pulse generation circuitry 40 and a second power source operative to provide power for the defibrillation shock generation circuitry 43.

Pilz, however, discloses an implantable pacemaker/defibrillation device (see Pilz Fig. 1, Abstract, column 1, lines 12-17 and column 5, lines 43-45) that has a significantly longer service life with respect to its base function, which has a low current consumption. The device of Pilz comprises a pacemaker circuit, read as pacing pulse generation circuitry 7, a high-current circuit for charging shock capacitors, read as defibrillation shock generation circuitry 5 including a shock capacitor (see Pilz Fig. 1 and column 6, lines 1-6), a Li/I battery, read as a first power source 1 operative to provide power for the pacing pulse generation circuitry 7 and a $LiMnO_2$ battery, read as a second power source 2 operative to provide power for the defibrillation shock generation circuitry 5 as long as the first battery still has enough power to operate the pacing pulse generation circuitry 7 (see Pilz Fig. 1, Abstract, column 2, lines 40-44 and lines 61-65, column 3, lines 35-67, column 4, lines 1-10 and column 5, lines 45-64). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Altman in view of Pilz to comprise a first power source operative to power the pacing pulse generation circuitry and a second power source operative to provide power for the defibrillation shock generation circuitry in order to provide an improved implantable pacemaker/defibrillator device that is capable of providing therapy for longer periods of time.

Response to Arguments

18. Applicant's arguments with respect to claims 1 and 23 have been considered but are moot in view of the new ground(s) of rejection.

19. Applicant's arguments, see page 8, third paragraph, filed July 18, 2006, with respect to Claim 13 have been fully considered and are persuasive. The 35 U.S.C. 103(a) rejection of April 19, 2006 has been withdrawn.

Terminal Disclaimer

20. The terminal disclaimer filed on July 18, 2006 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Allowable Subject Matter

21. Claim 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

22. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

Adams et al. (U.S. 5,372,605) teaches that it is well known in the art to provide an implantable pacemaker/defibrillator device with a first power supply for powering low voltage output circuit components with power (such as pacing and monitoring components) and a second power supply for powering high voltage output circuit components (such as cardioversion and defibrillation components) to extend the life of the device.

23. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The Examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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